

**K232555 Harmony**Nov 20, 2023  
89 days to decisionK232555 · Product code: **NFJ** · Ophthalmic  
Source: <https://www.510kdatabase.net/k232555/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Aug 23, 2023
Decision date	Nov 20, 2023
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Topcon Healthcare Solutions</b>
Location	Oakland, NJ, US
Contact	Tobias Schwarz
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Orasi Consulting, LLC</b>
Contact	Lena Sattler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232555/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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